

CHAPTER 6

6.0 RISK MANAGEMENT - INFORMATION NEEDED FOR DECISION-MAKING

6.1 INTRODUCTION

The NAS defines risk management as "a process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision" (NRC, 1983). NAS has identified four key components for managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC, 1994). Risk characterization is considered the "bridge" or "interface" between risk assessment and risk management. EPA recommends that risk characterization should be clearly presented and separated from any risk management considerations. EPA (1995a) policy indicates that risk management options should be developed using risk input and should be based on consideration of all relevant factors, both scientific and non-scientific.

Consistent with NAS, USACE has developed the HTRW RMDM process. This process identifies factors to consider when making decisions, developing and recommending options, and documenting of risk management decisions (Figures 6-1, 6-2). The process establishes a framework to manage risk on a site-specific basis. It emphasizes that risk management must consider the strengths, limitations, and uncertainties inherent in the risk assessment as well as other non-risk factors. The consideration of risk is critical, since site actions are driven by statutes and regulations which explicitly require the "protection of human health and the environment."²¹

²¹ Examples of these requirements are 40 CFR 300.430(e)(1) of the NCP for deciding if RA is needed for a CERCLA site; RCRA Sections 3004(u), 3004(v), 3008(h), 7003 and/or 3013 for requiring corrective actions at hazardous waste TSD facilities to protect human health and the environment; and the risk-based determination for NFA (40 CFR 264.514) and selection of remedy (40 CFR 264.525) under the proposed Subpart S RCRA corrective action rules.

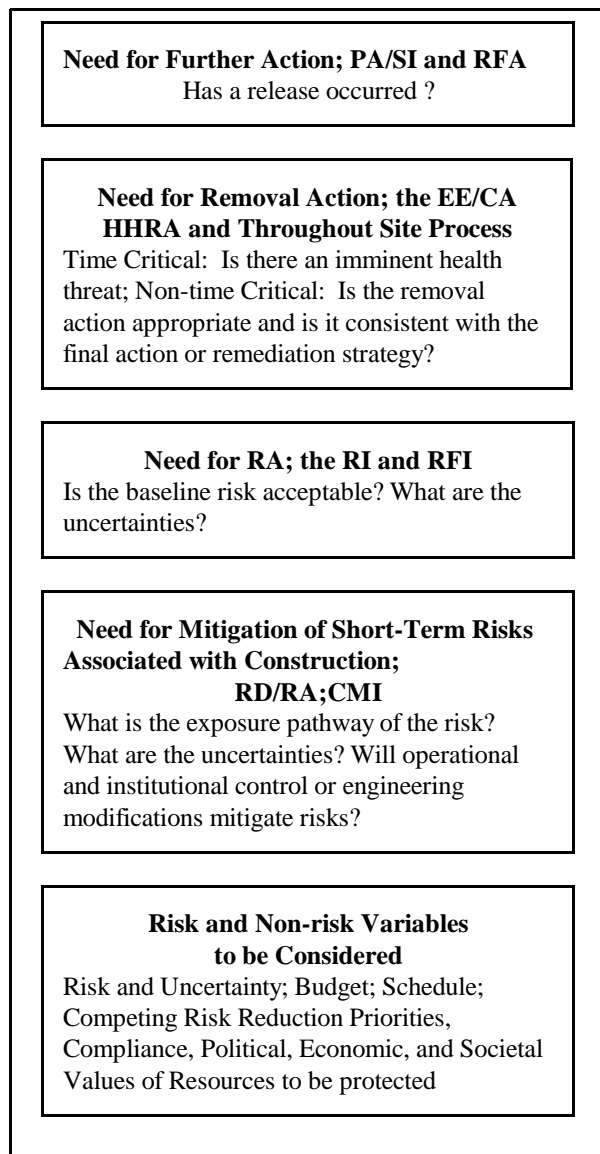


Figure 6-1. Inputs for Risk Management Decision-Making, HTRW Project Decision Diagram

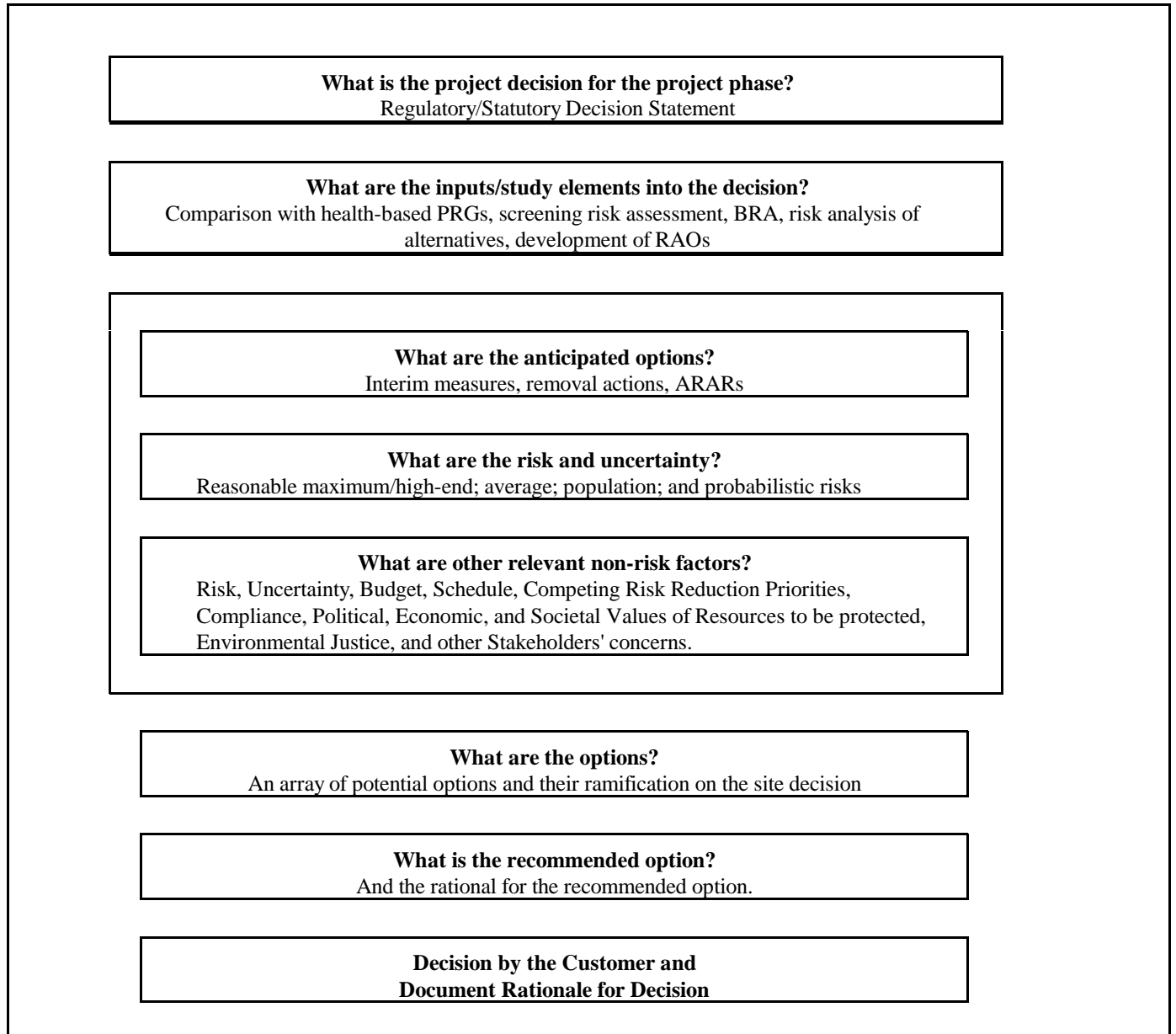


Figure 6-2. HTRW RMDM Process Flow Diagram.

Therefore, selecting the proper risk tool and collecting data to assess environmental risk is a primary responsibility of the PM and the risk assessor.

The Risk Assessment Shall be Given, at a Minimum, Equal Consideration with Other Factors in the Risk Management Decision

Too often, we are performing non-risk driven cleanups. Although many other factors enter into a risk management decision, the safety and health of the public, the workers, and the environment must be considered foremost. Where a sound, defensible risk assessment shows that there is little or no risk from contaminants at a site, resources should not be expended on additional study or remediation.

Additionally, data generated during the risk assessment must not be used out of context. Risk screening values must not be used as cleanup goals due to the conservative parameters used in their generation. RGs should be developed based on the calculations within the risk assessment in conjunction with the risk management decision regarding acceptable risks.

In addition to risk and uncertainty, there are many non-risk variables influencing the risk management decision. The major ones are cost, schedule, value of resources to be protected, competing risk reduction priorities among sites managed by the customer, compliance/regulatory, political, economic, and technical feasibility. A relatively sensitive political and/or economic factor to be considered is "Environmental Justice or Equity." This phrase relates to the government's initiatives to cleanup sites located in "poor and disadvantaged" areas.

The risk assessment, in conjunction with other important "non-risk" decision criteria, provides information on the need for remedial or early actions. Therefore, a clear understanding the risk assessment results and their uncertainties is essential. Informed RMDM will lead to protection of human health and the environment, cost savings, meeting the agreed schedule, political harmony, better management of resources, and other social and economic benefits. The HTRW RMDM process is

consistent with recent initiatives by various officials: Habicht (USEPA, 1992d), Denit (USEPA, 1993d), Browner (USEPA, 1995c), and DOD (1994a) that suggest the need for risk reduction based on "real world" or realistic risk assessment, cost benefit analysis, and prioritization of environmental issues.

Prior to gathering data and performing the HHRA, the PM defines the site decision for the project phase, the required study elements (types of HHRA or risk tools to be used), and the potential uncertainties associated with the outputs of the study element. Based on risk information and other considerations, the customer can select from an array of recommended risk management options. Options can include gathering additional data, recommending NFA, interim measures, or removal and/or RAs. To facilitate RMDM, the USACE PM should anticipate potential risk management options early in the project planning phase. Examples of the use of risk assessment in various project phases include:

- PA/SI or RFA: A screening risk assessment and an exposure pathways analysis may be performed to determine the need for further investigations.
- RI or RFI (prior to FS and CMS): The BRA determines the need for the RA.
- FS or CMS: Results of the BRA are used to develop RGs (i.e., the calculation of a target chemical concentration given a known target risk level or acceptable hazard).
- FS or CMS: Qualitative or quantitative risk assessments to compare and evaluate potential health impacts from the remedial alternatives. A qualitative or simple quantitative risk assessment (similar to the BRA) may be conducted to screen alternatives for their potential short-term and residual risks.
- RD (prior to conducting RA and CMI): Detailed risk analysis may be performed to determine if protective measures should be taken to minimize the impact to health and the environment during remediation. For example, a toxicity assessment may be conducted to evaluate the short-term acute, subchronic, and chronic toxicities of potential releases from the remediation process.

It is important to recognize that risk managers often make difficult decisions with considerable uncertainties in both risk and non-risk information. Therefore, a focused and balanced risk approach is recommended that recognizes the reasonable limits of uncertainty for the protection of human health and the environment as the primary consideration, along with the considerations for non-risk issues. The risk manager should clearly communicate the decision and the associated assumptions, and document the basis for the decision.

6.2 DETERMINING REQUIREMENTS FOR ACTION

The fundamental requirement associated with any HTRW response action is the "protection of human health and the environment." This requirement focuses on the acceptability of site risk or risks from the potential actions. EPA risk assessment guidelines (USEPA, 1989j), the NCP (USEPA, 1990c), and the proposed RCRA Corrective Action Rule (USEPA, 1990d) define acceptable risks of carcinogenic and noncarcinogenic effects. For carcinogens, the acceptable individual upper bound lifetime risks range from a probability of 1E-04 to 1E-06. For noncarcinogens, the acceptable hazard, expressed in terms of the sum of HQs for chemicals affecting similar organ systems or toxicological endpoints (HI), is unity. Depending on the exposure period of concern, the HQ is the average daily intake divided by the chronic or subchronic RfDs which are based on the No Observed Adverse Effects Level or the Lowest Observed Adverse Effects Level in human study or animal bioassays. Cancer risk is expressed as an individual excess lifetime risk, and is the chronic daily intake multiplied by the carcinogenic SF. Cancer risk or noncancer hazard estimates are based on the CSM specific for the site under baseline conditions, during site removal or RAs, and after remediation. Human activity patterns indicated in the CSMs are directly related to current and future land use. This paragraph presents the risk management options in key phases of the HTRW project life cycle.

6.2.1 PA/SI and RFA. The purpose of PA/SI under CERCLA and the RFA under RCRA is to identify if chemical releases have occurred, or if the site can be eliminated from further action. The PAs and RFAs are typically performed by the state, EPA, or the Federal agency, and are generally preliminary in nature. Under

some circumstances Federal agencies may perform these activities with greater depth and vigor under EO 12580. Unless good evidence exists that a site is contaminated, it is a crucial for the PM to methodically review each identified site, area of contamination, SWMU, and AOC, and decide if these units should be eliminated from the next project phase. In addition, it may be important to determine if an imminent health threat or a substantial site risk potentially exists that would require an early response action (e.g., non-time critical removal actions, interim measures, or IRA).

6.2.1.1 Actual or Potential Release/Exposure. Under the PA/SI or RFA phase, the risk management decision will be based on documented past spills and releases, the likelihood of such spills/releases, the presence of endangered or threatened species, sensitive environments or resources to be protected, and the existence of transport mechanisms that could bring the chemicals in contact with receptors.

6.2.1.2 ATSDR Health Advisories. The ATSDR performs health assessments to document or provide consultations on potential public health consequences associated with hazardous waste or Superfund sites. ATSDR representatives are located at all EPA regional offices and work cooperatively with the Superfund and RCRA staff. ATSDR involvement in the removal/emergency response program includes issuance of draft and final health advisories or consultations.

Before ATSDR health advisories are used as a basis for going forward into the next project phase or undertaking removal actions, the HTRW risk managers and PMs should contact the appropriate USACHPPM personnel for a detailed review of the health advisories to ascertain the strength and validity of the health advisories. This is recommended because the PA/SI or RFA data are quite tentative in nature, and oftentimes have not gone through a vigorous data validation process. For example, if unfiltered ground water data were used by ATSDR, and the samples had high turbidity, indicating insufficient development and purging of wells, the data should be questioned and, if feasible, new ground water data acquired to assess the need for RI, RFI, or potential removal actions.

In making risk management decisions concerning emergency response actions in this project phase, the risk

managers may be put in the position of accepting data or recommendations of a lesser degree of confidence or a higher degree of uncertainty.

6.2.1.3 Risk Screening and Prioritization of Units of Concern. Initial risk screening (Chapter 3) is an important tool for ranking or prioritizing sites (OUs/SWMUs). This tool can result in substantial savings of resources, allowing the implementation of a more focused site investigation. The risk screening results are likely to provide significant inputs into the RMDM for this project phase.²²

It is not uncommon to have tens or hundreds of "sites" or SWMUs within a site or facility boundary. Risk managers at these facilities are faced with potentially complex investigations. Rather than taking a "piece meal" approach of investigation, the list of sites or SWMUs should be pared down if possible. The risk manager may negotiate with the agencies and enter in the IAG or FFA to permit the use of an approach that "addresses the worst sites first," and at the same time, group SWMUs within the same EUs or geographical locations, as appropriate. This prioritization should result in the greatest benefit with limited available resources. Site prioritization should include the following:

- Eliminate sites or SWMUs administratively by record review, interviews with current and former workers, and ascertain whether the unit of concern meets the definition of a "SWMU."
- Conduct a site reconnaissance and group sites or SWMUs with common exposure pathways or EUs, if appropriate.
- Rank the remaining sites or groups of sites qualitatively or quantitatively based on the CSM or a screening risk analysis.

Generally, the above tools will serve well if they are objectively and uniformly applied. The use of site prioritization:

- Provides justification for NFA for low priority sites.
- Allows better resource allocation for investigation of the remaining sites.
- Helps identify potential boundaries where receptors are to be protected.
- Identifies high priority sites or SWMUs for emergency response, early actions, or accelerated cleanup or site stabilization.

The *Relative Risk Site Evaluation Primer* (DOD, 1994b) recommends evaluation based on three criteria: (1) contaminant hazard factor, (2) migration pathway factor, and (3) receptor factor. Information generated from the initial risk screening (Chapter 3) can be used as a decision-making basis using a similar site ranking process. Sites may be ranked high, medium, or low based on non-quantitative exposure pathway considerations such as the following:

1. Significant Contaminant Levels

- a. High Relative Risk: Sites with complete pathways (contamination in the media is moving away from the source) or potentially complete pathways in combination with identified receptor or potential receptors.
- b. Low Relative Risk: Sites with confined pathways (i.e., contaminants not likely to be

²² EPA's Deputy Administrator (USEPA, 1995a,c) is concerned with the need for assuring consistency while maintaining site-specific flexibility for making remedial decisions (from site screening through final risk management decisions) across programs. EPA stresses that priority setting is reiterative throughout the decision-making process because limited resources do not permit all contamination to be addressed at once or receive the same level of regulatory oversight. EPA suggests that remediation should be prioritized to limit serious risks to human health and the environment first, and then restore sites to current and reasonably expected future uses, whenever such restorations are practicable, attainable, and cost effective. EPA further suggests that in setting cleanup goals for individual sites, we must balance our desire to achieve permanent solutions and to preserve and restore media as a resource, with growing recognition of the magnitude of the universe of contaminated media and the ability of some cleanup problems to interact with another.

released or transported) and limited potential for receptors.

- c. Medium Relative Risk: Sites with characteristics not indicated in the above.

2. Moderate Contaminant Levels

- a. High Relative Risk: Sites with complete pathways or potentially complete pathways in combination with identified receptors; or sites with complete pathways in combination with potential receptors.
- b. Low Relative Risk: Sites with confined pathways and any receptor types (i.e., identified, potential, or limited potential), or sites with potentially complete pathways in combination with limited potential for receptors.
- c. Medium Relative Risk: Sites with characteristics not indicated in 2.a and 2.b above.

3. Minimum Contaminant Levels

- a. High Relative Risk: Sites with complete pathways in combination with identified receptors.
- b. Medium Relative Risk: Sites with potentially complete pathways in combination with identified receptors or sites with evident pathway in combination with potential receptors.
- c. Low Relative Risk: Sites with characteristics not indicated in 3.a and 3.b above.

The relative risk site ranking process may also be modified to include consideration of the degree of confidence in the relative risk rating. Sites with a low degree of confidence and a low relative risk may then be given a higher rating than sites with a high degree of confidence and a low degree of risk.

6.2.1.4 Risk Management Decisions and Options. Risk management decisions, risk information needs, risk

assessment tools to satisfy the information needs, and risk management options are presented in this section. "Non-risk" factors to be considered in the decision-making are presented in Section 6.2.4.

Risk Management Decision

- Should a site be eliminated from further investigation or included in the RI or RFI project phase?

Risk Management Options/Rationale

• **Further Evaluation Needed**

Rationale: If a site cannot be justified for NFA, further evaluation (Expanded SI; Extent of Contamination Study; RI or RFI) will be needed.

• **NFA**

Rationale:

- No knowledge of documented releases or major spills/low likelihood of spills/procedures existed to promptly cleanup all spills.
- Transport mechanisms do not exist, e.g., presence of secondary containment.
- The substances released are not expected to be present due to degradation and attenuation under the forces of the nature.
- Spills or releases have been addressed by other regulatory programs (e.g., the UST program or RCRA closure under Subpart G of 40 CFR 264 or 265).
- The unit does not meet the definition of a "SWMU."
- The unit is part of another identified unit or site which will be addressed separately.

Although risk assessment is traditionally performed in the RI or RFI project phases of HTRW response actions, risk assessment can assist the risk managers in all project phases. Results of risk assessment activities are used to answer three key questions:

- Whether or not there is a need to go forward with the next project phase.
- Whether or not early response actions (removal actions, interim measures, or IRAs) should be taken to mitigate potential risks.
- Effectiveness of the potential response action and the short-term risks associated with implementation of the removal actions.²³

Risk Management Decision

- Should early response action be undertaken to mitigate risk?

Risk Management Options/Rationale

• **No Early Response Action**

Rationale:

- Transport mechanisms probably do not exist, e.g., presence of secondary containment.
- Low concentration of site contaminants or the levels measured probably do not pose an acute hazard, and

²³ Removal actions must be flexible and tailored to specific needs of each site and applicability (i.e., complexity and consistency should be used in evaluating whether non-time critical removal actions are appropriate). Examples of removal actions are: (1) sampling drums, storage tanks, lagoons, surface water, ground water and the surrounding soil and air; (2) installing security fences and providing other security measures; (3) removing and disposing of containers and contaminated debris; (4) excavating contaminated soil and debris, and restoring the site (e.g., stabilization and providing a temporary landfill cap); (5) pumping out contaminated liquids from overflowing lagoons; (6) collecting contaminants through drainage systems (e.g., french drains or skimming devices); (7) providing alternate water supplies; (8) installing decontamination devices (e.g., air strippers to remove VOCs in residential homes); and (9) evacuating threatened individuals, and providing temporary shelter or relocation for these individuals (USEPA, 1990f).

it is questionable whether the levels pose unacceptable chronic risk or hazard.

- Site contaminants are not likely to be persistent or the contaminants are relatively immobile.

• **Early Response Action**

Rationale:

- There is no current impact, but if uncontrolled, the site could pose a substantial threat or endangerment to humans or the environment. (Examples are: physical hazard, acute risk from direct contact with media of the unit or site, or effluents or contaminated media are continuously being discharged to a sensitive environment.)
- The principal threat has reasonably been identified because of the evidence of adverse impacts. In this context, the COPCs are known and the exposure pathways are judged to be complete, e.g., the exposure point or medium has been shown to contain the COPCs.
- The boundary of contamination is reasonably well defined so that removal action(s) can be readily implemented.
- The early actions are consistent with the preferred final remedy anticipated by the customer, reducing risks to human or ecological receptors, or both.
- The response action will be used to demonstrate cessation or cleanup of releases, resulting in substantial environmental gain which is the basis for early site close-out or further investigation.
- High concentration (acute hazard level) of site contaminant is found in the exposure medium.
- Highly toxic chemicals or highly persistent and bioaccumulative chemicals found on-site which may be transported off-site.
- Non-complex site (no cost recovery issue, limited exposure pathways, small area sites, etc.).

Early response actions or removal actions, consistent with the final RA, may be taken at any time to prevent,

limit, or mitigate the impact of a release. To encourage early site closeout or cleanup, EPA has encouraged early response actions at sites where such actions are justified. To the extent possible the selected removal actions must contribute to the efficient performance of long-term RAs. EPA's *RCRA Corrective Action Stabilization Technologies* (USEPA, 1992n) and *SACM* (USEPA, 1992g) emphasizes controlling exposure and preventing further contaminant migration. While these concepts are intended to expedite site actions, risk assessment provides important information for justifying cleanup actions. The applicable risk assessment methods include:

- A screening risk analysis.
- Development of medium-specific short-term health goals for screening or comparison with modeled or site data.
- Qualitative evaluation of removal actions for their effectiveness to reduce exposure and risks.
- BRA may be appropriate for non-time-critical removal action and for complex sites (sites with multiple pathways, without ARARs, large geographic areas, and with a need for cost recovery).

In order to allow timely input into the RMDM for the removal actions or interim corrective measures, the risk assessment or risk analysis should be planned and conducted in a timely manner. If removal actions are straightforward, e.g., addressing hot spot areas or high concentration plumes, the risks associated with removal actions will then be evaluated for their potential short-term risks and hazards for the specific removal actions. The short-term risks or threats to workers and other human receptors may be based on one or more of the following:

- Air, soil, surface water, ground water (including drinking water), and food chain contamination.
- Direct (dermal) contact with contaminated media.
- Ingestion of contaminated media or inhalation of contaminated air or particulate matter.
- Fire/explosion hazard.

Early actions or accelerated cleanup can often be justified as long as the actions are consistent with the preferred site remedy. Since remedies are generally not selected until late in the FS or CMS, the customer's concept of site closeout and anticipated action is critical for deciding which types of early actions are appropriate. Based on experience gained in the Superfund program, EPA has identified certain site types where final remedies are anticipated to be the same (presumptive remedies). The current list of presumptive remedies includes:

- Municipal landfill - capping and ground water monitoring.
- Wood treatment facility - soil and ground water remediation.
- Ground water contamination with VOCs - air stripping/capture wells.
- Soil contamination with VOCs - soil vapor extraction.

6.2.1.5 Qualitative Evaluation of Response Actions for Their Effectiveness to Reduce Risks. Removal of hot spots can provide substantial improvements in the site environment. In some cases, actions can drastically reduce exposure to receptors and allow natural attenuation to further reduce the exposure point concentration. If removal actions are needed, the risk manager should request two types of risk information. First, if there is more than one removal option, what is the comparative effectiveness of the options to reduce exposure and risks? Second, what is the risk or environmental impact associated with the proposed removal action? To answer the first question, the HTRW risk assessor or risk manager provides information on how the removal option can eliminate risk or reduce the level of exposure both on-site and off-site, if contaminant migration has occurred to off-site exposure points. If substantial risk reduction can be obtained by all options, the risk manager should consider other factors, such as effectiveness, reliability, etc. To answer the second question, the project engineer estimates the destruction or treatment efficiency of the medium to be treated or disposed, and the type/quantity of wastes or contaminated debris to be generated for each potential option. This information is important if an action is

likely to generate waste or damage sensitive environments in the course of the remediation.

It is important to communicate and obtain an early buy-in of the removal action from the local community. If the proposed removal actions are likely to pose unacceptable short-term risks to on-site or off-site receptors, the removal action should either be discarded or monitoring/control measures be instituted. (As discussed later, the risk assessor and HTRW TPP team members provide options for making decisions when there are divergent interests between the protection of humans and the protection of ecological receptors of concern.) The risk assessor should work with other project team members to evaluate the potential for chemical releases or habitat destruction potentially associated with a remedial option. These evaluations should be qualitative and not extensive, and can be based on a consensus of professional judgement/opinion. These individuals should recommend alternatives or precautionary/protective measures to the risk manager to mitigate any potential risks.

6.2.2 RI/RFI. The primary objective of RFI, RI, or other equivalent HTRW project phases is to determine if site contamination could pose potentially unacceptable human health or environmental risks. Determination of unacceptable risk, according to the NCP, is identified through a BRA under RME. The RCRA corrective action process is similar to Superfund for determining the need for remediation, albeit initially, the TSDF owner/operator may simply compare a specific set of SWMU data with established health-based criteria. EPA generally considers performance of a HEA to be functionally equivalent to the Superfund BRA (both human health and ecological) in the RI/FS. While a few EPA regions have developed separate guidelines for RCRA, there is a national effort underway as well. The RCRA HEA should be conducted prior to or early in the CMS to determine the need for corrective measure implementation.

If the Cumulative Site Risk Calculated in the BRA Does Not Exceed 1E-04 for Reasonable Exposure Scenarios, ARARs are Not Exceeded, and Ecological Impacts are Not Significant, No RA Should be Required.

Remediation beyond risk levels has resulted in the expenditure of excessive tax dollars. Where remediation is not justified by risk or the exceedance of ARARs, it should not be done. This point is summarized by EPA: "Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 1E-04, and the non-carcinogenic HQ is less than 1, action generally is not warranted unless there are adverse environmental impacts." (USEPA, 1991a)

The BRA or HEA associated with the RI/RFI project phase can assist the RMDM process in the following ways:

- The BRA, performed in the RI/FS or RFI project phase, presents the degree of potential carcinogenic risks and noncarcinogenic hazards posed by the site to humans (individuals and populations), and the associated uncertainty. Risks can be estimated for the entire site, OUs, AOCs, and SWMUs.
- The results of the BRA can be used to answer the questions relating to the site decisions on: (1) whether or not there is a need to go forward with the next project phase (i.e., RD/RA needed or no action alternative); and (2) whether or not removal actions (interim corrective measures) should be implemented to mitigate potential risks, which are consistent with final action.
- If a site poses unacceptable chronic hazard or carcinogenic risk, remediation will be needed for pathways indicated in EUs. Pathways/EUs which do not pose an unacceptable risk may be eliminated from further concern. The algorithms developed in the BRA can be used in reverse to develop site-specific health-based RGs (cleanup levels) in the FS.

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The above determinative factors are considered in the review of the BRA summary (and uncertainty) by the risk manager, along with other non-risk criteria in the RMDM. It should be noted that the decision could be partial, i.e., some SWMUs or sites within the facility will require remediation/removal actions while others do not.

Risk Management Decision

- Should RA or corrective measure be required based on the BRA?

Risk Management Options/Rationale

• **NFA Needed**

Rationale:

- No acute or chronic hazards or risks to humans under current and future exposure (land use) conditions/low likelihood of exposure by the receptors.
- Transport mechanisms probably do not exist.
- Low concentration of site contaminants or the levels measured probably do not pose acute and chronic hazard and carcinogenic risk.
- There is no anticipated risk of physical hazards.
- Site contaminants are not likely to be persistent or the contaminants are relatively immobile.
- Technically not feasible or impractical (e.g., dense non-aqueous phase liquid) in an aquifer not anticipated to be used for human consumption.
- **Time-Critical Emergency Response Action Needed**

Rationale:

- A high likelihood of releases and transport of site contaminants to receptors, e.g., ground water plume is migrating to onsite or offsite drinking water wells.
- A high risk of physical hazards.

- High concentration (acute hazard level) of site contaminant is found in the exposure medium.
- Highly toxic chemicals or potent carcinogens are found onsite which may be transported offsite.
- Documented unacceptable drinking water or surface water contamination, which is contacted or consumed by humans.
- **Non-Time-Critical Removal Action, Interim Corrective Measures, or Accelerated Cleanup**

Rationale:

- Principal threat to human health has been identified. If unabated, there is a potential of injury, chronic risk to humans or the environment.
- Presumptive remedies available for the identified sites or SWMUs.
- Transport mechanisms are available.
- The exposure pathway was the basis for NPL listing, or past or ongoing enforcement actions on spills or releases.
- The response action is generally consistent with the preferred site remedy, and there are no complicating factors.
- Control of migration should be taken soon, or risk the exposure of site chemicals to human receptors or valuable community resources.
- The early action will result in an incremental gain in environment benefit (including ecological), plus substantial savings in future remediation expense.
- **FS (CMS) Remediation Warranted**

Rationale:

- Unacceptable hazards and risks involving multiple chemicals and exposure pathways. If unremediated, there is a long-term threat to humans and other resources.

- Transport mechanisms are available.
- Site-specific conditions (geology or location, etc.) are unique or unusual and require detailed evaluation of remedies.
- Unusual chemicals present on site which will require bench-scale and pilot-scale studies.
- **NFA Needed Except Periodic or Continuous Monitoring**

Rationale:

- RCRA facility is operating and expected to continue for the anticipated future.
- Interim corrective measures or removal actions in place which have effectively controlled migration of site contaminants and exposure.
- Baseline risk estimates are within the acceptable range and the exposure (land use) remains in the anticipated future.
- Institutional controls are deemed adequate to control exposure.
- Toxicity of the COC, which causes the principal threat is tentative, albeit the risk or hazard has been exceeded.
- The baseline risk estimates are uncertain and there are no readily available transport media for exposure (e.g., public water supply is available in the area) or COCs are subject to natural dilution and attenuation.

6.2.3 FS/CMS and RD/RA. The FS or CMS is triggered when the baseline risk is unacceptable and remediation is needed to mitigate risks and prevent further contaminant migration. In some instances, the FS or CMS could be driven by a legal requirement to meet ARARs, although ARARs are not necessarily risk-based. The FS or CMS evaluates potential remedial alternatives according to established criteria in order to identify the appropriate remedial alternative(s). The FS or CMS can be performed for the entire site or any portion of the site that poses unacceptable risks. The results of the FS/CMS include recommendations for the risk managers or site

decision-makers, including an array of remedies for selection, RAOs, or TCLs for verification of cleanup.²⁴ The selected remedies/TCLs or revisions thereof will be entered into the ROD or the Part B permit.

Risk Management Decision

• **What are the RAOs?**

Risk Management Options/Rationale

The risk management decision for selection of final remedies depends substantially on the RAOs. Uses of RAOs are summarized below:

- Developed or agreed upon by the agencies prior to the FS or signing of the ROD (or modification of the RCRA permit), RAOs are used to evaluate the feasibility of candidate remediation technology in the FS.
- Initial estimation and costing of remediation (e.g., excavation and stabilization).
- Delineation of cut lines for remediation.
- For use in negotiation or final determination of specific areas, SWMUs or site-wide cleanup goals, by considering uncertainties, technology, and cost.

Before embarking on an FS, RAOs should be developed using site-specific risk information consistent with site conditions. Factors to be considered when RAOs are used as the basis for designing and implementing remediation are presented below:

6.2.3.1 RAOs Must be Based on CSM. The CSM provides the framework for the BRA and identifies the specific pathways of concern. RAOs must be able to

²⁴ For the purpose of protecting the environment, the TCLs (sometimes known as RAOs) may be the same as the environmental-based preliminary remediation levels, or they may be different. TCLs or RAOs are negotiated levels for verification of the proposed cleanup technology, practical QLs (PQLs), and uncertainties associated with the preliminary remediation levels to protect ecological resources of concern.

address these pathways and the associated risks. A refined CSM, based on the results of the BRA is paramount to the establishment of focused RAOs. The RAOs are based on preliminary remediation levels developed as the project strategy goals in Phase I of the HTRW project planning under RI/FS or RFI/CMS.

6.2.3.2 RGs Must Be Protective and Practical. RGs are performance and numerical objectives developed in the FS/CMS to assure that the remedial alternative will contribute to site remediation, restoration, and closeout/delisting. As such, they must be protective and workable. To assure protectiveness, risk-based RGs should be first derived using the BRA procedures in reverse (USEPA, 1991d). The uncertainty associated with development of the RGs should be discussed and quantified. Site decision-makers carefully consider technology, PQLs, ARARs, or TBC criteria, reference location concentrations, acceptable hazards, field or laboratory analytical uncertainties, etc., before setting the RAOs.²⁵

6.2.3.3 Action Must Be Consistent with Other Project Phases. Understanding of the nature and extent of contamination, as well as the media and exposure pathways of concern, is a critical requirement for successful completion of the FS or CMS and remedy selection. Therefore, data used in the FS or CMS must interface with the RI/RFI and other previously collected site data. Inadequate data or data of poor quality misrepresent site contamination and may lead to an inadequate BRA and FS. For each exposure pathway that presents an unacceptable risk, the risk assessor and the appropriate project team members (e.g., chemist, geologist, or hydrogeologist) should review the RI data before conducting the FS. This is particularly important when the FS is performed simultaneously with the RI, based on assumptions and PA/SI or RFA data.

²⁵ Certain sites may be contaminated with natural or anthropogenic substances which pose matrix interferences and cause high sample DLs (i.e., the QLs may be higher than the environmental-based PRGs). For these sites, it may be advantageous to design a representative sampling program of the background medium to establish QLs for use as alternative RGs.

Minimal information or guidance has been developed by EPA regarding the development of RAOs for RCRA and Superfund sites. RCRA has issued the ACL Guidance based on 264.94(b) criteria and case studies (USEPA, 1988f) which may be applied to developing ACLs at the source if the acceptable ground water/surface water mixing zone concentrations and the dilution/attenuation factors are defined. Under the proposed Subpart S rule for RCRA corrective action, the state water quality criteria can be used to screen if a CMS should be conducted. Nonetheless, the key risk management issue concerning the above is that the cleanup goals must be practical and verifiable. When cleanup goals are developed to protect both humans and ecological receptors, according to Section 300.340 of the NCP, the goals must be so adjusted that both receptor types are protected.

Environmental and human health-based RAOs should be developed together and proposed to the risk manager and agencies for use in the CMS for the evaluation of remedial alternatives. It should be noted that the RAOs may have to be revised or refined based on other considerations, e.g., technology, matrix effects, target risks, uncertainties, and costs (associated with the extent of the remediation, management of remediation wastes, cost of cleanup verification analyses).

Risk Management Decision

- **What are the Remedial Alternatives or Corrective Measures?**
- **What are the Preferred or Optimal Remedial Alternatives?**

Risk Management Options/Rationale

In addition to a cost and engineering evaluation of the potential remedial alternatives, each alternative must be evaluated for its ability to reduce site risk. Among the nine criteria identified by the NCP for remedy selection, protection of human health and the environment and satisfying ARARs are considered to be the threshold (fundamental) criteria which must be met by any selected remedy. More recently, EPA has placed increased emphasis on short- and long-term reliability, cost, and stakeholders' acceptance in the overall goal to select remedies. Therefore, the assessment of residual risk (a

measure of the extent of site risk reduction) is a critical task.

Screening and detailed analyses of remedial alternatives will be conducted in the FS and CMS project phase. The preferred remedial alternative will be proposed. As warranted, analysis of short-term risks to assess the need for control measures will be conducted in the RD project phase, and the control measure(s), if appropriate, will also be proposed.

In the FS, potential risk reductions associated with remedial alternatives are assessed. The relative success of one alternative over another is simply the ratio of the residual COC concentrations in the exposure medium of concern. This screening evaluation does not take into account short-term risks posed by the alternative or technology due to acute hazards, releases, or spills.

6.2.3.4 Screening Evaluation of Alternatives. This evaluation focuses on determination of short-term risks posed by the removal or remedial alternatives. The findings of this evaluation are compared among the alternatives to determine preferred remedies based on the effectiveness of the remedies to satisfy RAOs with the least impact. This screening evaluation should focus primarily on effectiveness, risk reduction, and cost.

Risk screening of alternatives should generally be qualitative or semi-quantitative. If a remedy has already been selected or is highly desirable for selection, a detailed risk analysis may not be needed. Instead, the evaluation should focus on the risk reduction of the preferred remedy, and identify any concerns or data gaps which need to be addressed. The data needed to perform this screening evaluation may come from many sources: RI or RFI data, bench scale or pilot scale treatability studies conducted for the site or from comparable sites, compatibility test, test of hazardous characteristics, field monitoring measurements, vendor's or manufacturer's information, literature values, and professional judgment.²⁶ Key information needed prior

to conducting the screening evaluation of remedial alternatives includes:

- Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal start-up and shut-down operations).
- Toxicity of chemical substances or COCs in the above discharges.
- Potential for dilution and attenuation.
- Existence of exposure pathways and likelihood of the pathways to be significant and complete.
- Potential for spill or releases during remediation, material handling, storage and transportation of remediation wastes.
- Potential for the causation of non-chemical environmental stressors such as destruction of critical habitat for threatened and endangered species, wetlands, or other sensitive environments.
- Temporal attributes associated with a RA which could be altered to reduce the action's impact.
- Potential release of additional COCs to the environment (e.g., re-suspension of toxic sediments during dredging, and changes of pH, redox potential, oxygen, and chemical state that may increase solubility and bioavailability).

The following are lists of qualitative evaluation criteria:

- **Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction)**
- Able to remove, contain or effectively treat site COCs.

²⁶ The bench scale or pilot scale treatability studies may provide valuable information for the estimation of remedial action or residual risks. Treatability studies provide data or information on the degree of removal and/or destruction of the COCs, quantity and identity of chemicals in the emissions or effluent discharges, and potential treatment standards to be applied to satisfy RAOs. This information

is important to quantify the magnitude of risk reduction and will be useful in the comparative analysis of potential remedial alternatives.

- Able to address the exposure pathways and media of concern.
- Able to meet the RAOs and overall project strategy goals.
- **Assessment of Residual Risk Potential**
- Reasonable anticipated future land use.
- Quantity of residues or discharges to remain on site.
- Toxicological properties of the residues.
- Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities, vapor pressure, density, etc.).
- Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).
- Potential for dilution and attenuation for residues released into the environment.
- The extent of, and permanence of, remediation, habitat destruction and alteration; e.g. the construction of an access road through wetlands would be considered permanent.

6.2.3.5 Detailed Analysis of Alternatives. Detailed analysis is usually conducted for the preferred remedial alternatives (or removal actions) identified in the screening evaluation described above. This detailed analysis has three objectives: (a) detailed assessment of potential short-term risk during RA, and residual risks if appropriate; (b) assess the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives; and (c) identify potential risk mitigation measures for the preferred remedies. The findings of these tasks are presented for final selection of remedies prior to ROD sign-off or RCRA Part B permit modification. All preferred remedies or options should satisfy RGs and should pose minimum health and environmental impact.

This evaluation may be qualitative, semi-quantitative, or quantitative. If the analysis is quantitative, procedures and approaches similar to the BRA may be followed. The *Air/Superfund National Technical Guidance Study Series* (USEPA, 1989a, 1990d, 1992o, 1993c, and 1995b) includes documents providing guidance for rapid assessment of exposure and risk. For example, guidance on determining the volume of soil particulates generated during excavation is provided in *Estimation of Air Impacts for the Excavation of Contaminated Soil* (USEPA, 1992b). The data sources used to perform this risk analysis task should be similar to those identified for the screening evaluation of remedial alternatives. Although it is conceivable that the level of effort required for this analysis may be high (particularly if the same analysis has to be performed for a number of preferred remedies), it is anticipated that the documentation and report writing will be focused and streamlined.

The report should focus on the risk analysis approaches, sources of data, findings/recommendations for risk mitigation measures, and appendices. Key factors or criteria to be considered in the screening evaluation of remedial alternatives are:

- The criteria or considerations in the assessment of short-term and residual risks are substantially similar to those identified for the screening evaluation of remedial alternatives. The key difference may be additional use of quantitative data input into the risk calculations, e.g., sediment transport modeling to evaluate the potential for migration of toxic sediment, amount of discharges or emissions, dilution/attenuation or atmospheric dispersion factors, exposure frequency, duration, and other activity patterns which could impact existing vegetation and wild life in time and space.
- Time required and extent of recovery from exposure to the COCs.
- The potential for fire, explosion, spill, and release of COCs from management practice of excavated or dredged materials should remain qualitative or semi-quantitative. Fault-tree (engineering) analysis for accidental events may be attempted under special circumstances (e.g., to address public comments or if demanded by citizens during public hearing of the proposed remedies).

6.2.3.6 Risks from Simultaneous Implementation of Preferred Remedies.

- Common exposure pathways for effluent or discharges from remedies.
- Period of exposure to receptors via the common locations, time, and pathways.
- Sensitive environments and other threatened or sensitive wildlife or aquatic populations.
- Risk estimates or characterization results.
- Toxicological evaluation for the validity of additivity of risk (e.g., under the Quotient Method), based on literature review, mode of action, and common target organs, etc.
- Qualitative or quantitative assessment of potential short-term or residual risks.

Short-Term Risks Associated with Construction; the Design Risk Analysis

All removal or remedial alternatives have a potential to pose short-term risks to on-site mitigation workers, ecological receptors, and off-site humans. Risks may be associated with vapors, airborne particles, treatment effluent, resuspension of sediment resulting in an increase in the total suspended solids or siltation of substrate for macroinvertebrates, and residues generated during operation of the remedial alternative. Therefore, all the alternatives should be reviewed for their short-term risks in conjunction with data from their bench scale or pilot scale treatability studies or data from implementation of the remedy at comparable sites. The risk assessor should estimate the period of recovery from these short-term insults and determine if biological or chemical monitoring of the effects of remediation activities should be implemented. For all practical purposes, risk may remain upon completion of the RA (residual risk).

Long-Term Risks Associated with Alternatives; the Residual Risks

Unless all sources of contamination are removed or isolated, there will be residual risks at the site upon

completion of the RA. The COC residuals could either remain or be quickly degraded, depending on the COC's physical and chemical properties. The level of residual risk will depend on the effectiveness of the remedy in containing, treating or removing site contaminants, and the quantity, and physical, chemical, and toxicological characteristics of residues or byproducts remaining at the site. Site COCs which remain on-site after the RA should be assessed for their potential risks.

This evaluation step focuses on a risk reduction assessment to determine if a potential remedial alternative is able to meet the RAOs, and an assessment of residual risk potential. The findings of these tasks are compared among the alternatives to determine an array of preferred remedies based on the effectiveness of the remedies to satisfy RAOs with the least long-term health and environmental impacts.

RA/Residual Risks vs. Baseline Risk

There are notable differences between RA/residual risks and the baseline risk. The key difference is that baseline risk refers to the potential risk to receptors under the "no remedial action" alternative, and RA and residual risks refer to short-term risks during RA and long-term risks which may remain after completion of the RA, respectively. Residual risk may be considered comparable to baseline risk after remediation, since in both cases the risks are chronic or subchronic in nature. RA risks are generally short-term (acute or subchronic) risks.²⁷

6.2.4 Non-Risk Issues or Criteria as Determining Factors for Actions. The NCP recognizes that it is not possible to achieve zero risk in environmental cleanup; therefore, the approach taken by Superfund is to accept

²⁷ One exception (i.e., remedial risk which is long-term) is a pump-and-treat remedy of ground water to meet MCLs for organics which pose a threat to human health but not ecological receptors. If the effluent is discharged to a surface water body and happens to contain trace elements at high levels (or other COCs not reduced by the treatment process), then an exposure route to environmental receptors may remain which is not addressed by the BRA, and which will exist for the operational lifetime of the remedy.

non-zero risk and return the site to its best current use (not to conditions of a pre-industrialization era). Under RCRA, the preamble to the proposed Subpart S recognizes that cleanup beyond the current industrial land use should be justified. This section presents and discusses the non-risk factors, and recommends a balanced approach for resolution of issues to enable quality RMDM. These factors can be categorized into scientific and non-scientific factors, as explained below.

6.2.4.1 Scientific Factors. The scientific factors, including engineering design and feasibility, should be considered in RMDM. These factors focus on technology transfer (realistic performance of the technology), duration of protection, and FS data uncertainties. These factors will influence the decision whether or not to proceed with selection of a particular remedy. They are detailed below:

Technology Transfer. This factor concerns the treatability of the contaminated debris or media by a preferred technology or early action. Although the recommended technology may appear attractive, a number of problems must be overcome before actual selection or implementation of the action. The following are a few examples:

- Scale up.
- Downtime and maintenance (including supplies).
- Ownership/control.
- Throughput to meet the required completion schedule.
- Skills required or training requirements.
- QLs and DLs.
- Space requirements for the remediation process and management of remediation wastes.

Duration of Protection. This factor concerns the duration of the removal or remedial technology designed to treat or address site risk. This factor is particularly important for site radionuclides or non-aqueous phase liquid compounds in the aquifer. The maintenance or replacement of barriers or equipment is also a primary

concern for this factor. Although a technology or alternative is effective, its effectiveness may not last long if there is no source control or contamination from off-site sources is not controlled

Data Uncertainty. This factor considers reliability and uncertainty of certain site or FS data for use in selecting a remedy, or for determining whether NFA is appropriate. Uncertainty in the following data may also impact the risk analyses or BRA results:

- Adequacy of bench-scale or pilot-scale treatability data.
- Data uncertainties (volume, matrices, site geology/hydrogeology).
- Field data and modeling data.
- Overall uncertainty of the source of site contamination.

6.2.4.2 Non-Scientific Factors. Non-scientific factors should also be considered in RMDM because some of these factors are key to a successful site remediation. Most of these factors are internal, but can also be external. Examples of these factors are enforcement, compliance, schedule, budget, competing risk reduction priorities, community inputs, and societal/economic value of the resources to be protected. These factors will influence the decision on whether or not certain removal or RAs should be taken, or on which remedies are to be selected. These factors are detailed below.

Enforcement and Compliance. Certain courses of action (including risk management decisions) have been agreed upon early in the process and have been incorporated in the IAG or FFA. This is particularly germane to some earlier HTRW sites. Nonetheless, the requirements specified in the enforcement documents or administrative order of consent, IAG, FFA should be followed by the risk manager or PM with few exceptions. When risk-related factors or other non-risk factors are over-arching, the risk manager should then raise this issue to higher echelon or to the legal department for further action or negotiation.

Competing Risk Reduction Priorities. Although related to risk, this factor represents the competing interest among programs or within the project for a limited source of funding to perform risk reduction activities. Since it is likely that not all sites will be cleaned up at an equal pace, the planning and execution of environmental restoration among these units should follow a prioritization scheme. However, the scheme developed according to risk may not be the same according to the customer, the base commander, or the agencies. The risk manager or PM must seek common ground to resolve this issue so that resources can be expended to produce incremental environmental benefits.

Schedule and Budget. These factors usually go together because the more protracted the project life, the more resources the project will demand. While each PM would like to comply with risk-based considerations with little margin of error, the PM may have no choice but to make risk management decisions with larger uncertainties than he or she would prefer, due to schedule and budget constraints.

Community Input. Opportunity for the stakeholders or community to provide input into the permit modification is provided when primary documents are prepared, i.e., RFI Work Plan, RFI/CMS reports, the proposed remedies, and the CMI Work Plan. Superfund also provides similar opportunities for public participation. To be successful in site remediation and closeout, the risk managers must be able to communicate risks effectively in plain and clear language without bias. Early planning and solicitation of community input is essential to democratization of RMDM. Some of the following issues may be of concern to the communities:

- Ineffective communication of risks and uncertainties.
- Lack of action (some action is preferred to no action).
- Not in my backyard (off-site transportation of contaminated soil, debris or sediment should avoid residential neighborhoods).
- Any treatment effluent or discharge is unacceptable (on-site incineration is seldom a preferred option except for mobile incinerators, in certain instances).

- The remedy should not impede economic growth or diminish current economic and recreational value of resources to be protected.
- Cleanup will improve the quality of life and increase property values or restoration of recreational or economic resources.

Societal/Economic Value of the Resources to be Protected. This non-risk factor concerns the community sentiment on how fast or in what manner the resources impacted by site contaminants should be restored. These resources may include surface water bodies, wildlife, and game animals. Most communities would like to see impacted resources restored to original use, however, this can be difficult to achieve. Some communities may be willing to accept natural attenuation or no action options for impacted surface water bodies, given the opportunity to examine the pros and cons of all options. Therefore, it is recommended that the risk manager execute a community relations plan in earnest in order to solicit the citizens' input on the risk reduction approach and issues of concern. Key community spokespersons may also be appointed to the site action committee to facilitate such dialogue and communication.

6.2.4.3 A Balanced Approach. In conclusion, the risk manager should consider all risk and non-risk criteria before making risk management site decisions. Due to uncertainties associated with risk assessment or analysis, the decision-maker must review risk findings and the underlying uncertainties, and consider other non-risk factors in the overall risk management equation. When making risk management decisions, the risk manager should keep an open mind regarding the approaches to meet the project objective. In order to make informed site decisions, the risk assessor must present risk estimates in an unbiased manner. With an understanding of the volume of contaminants of concern, significance and relevance of the effects and potentially impacted receptors, fate/transport properties of the COCs, and completeness of the exposure pathways, the risk manager, PM, and stakeholders will be better equipped to make informed decisions. These decisions should be consistent with the overall site strategy, which is developed early in the project planning phase, and which may evolve throughout the project.

6.3 DESIGN CONSIDERATIONS

Risk assessment methodology can be an important tool in the design phase of CERCLA RAs or RCRA corrective measure implementation. During the early phase of RD/RA or CMI, risk assessment results can help determine: 1) whether the selected remedy can be implemented without posing an unacceptable short-term risk or residual risk; and 2) control measures (operational or engineering) to mitigate site risks and to assure compliance with ARARs, TBC requirements, and permit conditions. The risk and safety hazard information will be evaluated by the site decision-makers, along with information concerning design criteria, performance goals, monitoring/compliance requirements prior to making risk management decisions regarding the above questions. Further, the decision-makers consider potential requirements such as ARARs and TBCs in determining design changes or control measures.

This section addresses the above issues, i.e., risk management considerations in RD, compliance with ARARs, including the CAA, CWA, ESA, and other major environmental statutes, and control measures required to mitigate risks.

6.3.1 Potential Risk Mitigation Measures.

Engineering Control - Where appropriate (when short-term risks are determined to be unacceptable), engineering controls should be recommended by the design engineer with inputs from the risk assessor, ecologist, compliance specialist, and the air modeler. Examples of these control measures include:

- VOC and Semi-Volatile Organic Compounds (SVOC) emissions - activated carbon canisters, after burners, or flaring, prior to venting.
- Metals and SVOC airborne particles - wetting of work areas; particulate filter/bag house, wet scrubber, or electrostatic precipitator (for thermal treatment devices or incinerators).
- Fugitive emissions - monitoring of valves, pipe joints, and vessel openings; and barrier/enclosure of work areas (e.g., a can or shield over the auger stem).
- Neutralization or chemical deactivation of effluent (continuous process or batch).
- Use of remote control vehicle for handling, opening, or cutting of drums containing explosive or highly reactive or toxic substances.
- Establish short-term trigger levels which will require work stoppage or upgrade of the remediation procedures (e.g., dredging of toxic sediments). Either biological or chemical indicators, or their combination could be used as the trigger levels. These levels should be developed in the RD/RA or CMI project phase by the risk assessor and other technical specialists, including the modeler.
- Consistent with the above trigger or acute concern levels, evaluate on-site performance with field equipment to assure adequate remediation.
- Afford the proper protection of sensitive environments by careful planning and positioning of staging area, storage or management of remediation wastes, selection of equipment with low load bearing, and season or time period when the remediation should be completed.
- Establish a zone of decontamination and proper management of effluent or waste generated from this zone.
- Secure and control access to areas where RAs are being implemented at all time.

6.3.1.1 Operational Control. Where appropriate, administrative control measures (procedural and operational) safeguards should be recommended by the PM, design engineer, or field supervisor during RA, with inputs from the risk assessor and other relevant technical and compliance specialists. Examples of these control measures include:

6.3.1.2 Institutional Control. Institutional controls are particularly pertinent for remedies which involve containment, on-site disposal of wastes, or wetlands remediation. Institutional controls should be recommended by the customer, PM, and other site decision-makers. Examples of these control measures include:

- Recording land use restrictions in the deeds (deed restrictions) for future use of certain parcels or areas where hazardous substances or wastes are contained.
- Erection of placards, labels, and markers which communicate areas where human exposure may pose short-term or residual risks.
- Security fences and barriers.

6.3.2 Risk Management; Degree of Protectiveness.

Not only should a selected RA (corrective measure) be able to meet balancing criteria, the RA must be protective, i.e., in terms of reducing site risks. In designing a selected remedy, the site decision-makers may face operational or engineering issues which are likely to require risk management decisions. For example, if a detailed analysis of a selected remedy reveals potential short-term or residual risks, the decision-makers must decide to what extent and with what control measures are necessary to abate the risk. Inputs from the risk assessor will be needed to help make informed risk management decisions. The following are examples of key risk management considerations for designing an effective remediation strategy:

- **Acceptability of control measures.** There are potential operational (procedural) or engineering control measures to address the short-term risks. The risk assessor, in coordination with the design engineer, expert ecologist(s)/advisory panel, and other project team members, assesses the effectiveness of any proposed control measures.
- **Removal of control measures.** Before a control measure is implemented, the decision on the minimum performance and when to stop requiring the control measure has to be addressed. This is particularly important if control measures are costly to implement and maintain.
- **Effectiveness of the remediation.** Remediation should effectively address on-site contamination if there is an continuing off-site (regional) source. This consideration is particularly important for ground water and sediment contamination remediation. This regional source control strategy should not be confused with the identification of Potentially Responsible Parties since some of the

discharges could be a permitted activity. Nonetheless, this issue has to be resolved if the RAOs are risk-based and do not consider off-site influences or contribution to the contaminants requiring remediation. Off-site source control and containment, waste minimization, and closure issues should be raised by the risk manager to the agencies, USACE customers, and higher echelon.

- **BRAC.** With BRAC, the land use of closed defense facilities may not be indefinitely controlled and the legislation governing BRAC holds the U.S. government responsible for future cleanup of contamination caused by government activities. Cleanup criteria and long-term remedies should take land use into consideration for implementation of an effective site closeout strategy. For example, conversion of a military base into a state park or refuge area will require different cleanup objectives than cleanup to the level acceptable for industrial/commercial usage. This issue should be addressed early in the site strategy development phase with input from customers, local re-development commissions, state, and other stakeholders.
- **Verification of cleanup.** The risk management decision concerning verification of cleanup, i.e., the numerical value of the RAO, should be based on a combination of factors: risk, uncertainty, statistics, analytical DLs/matrices, and costs. Although RAOs have been negotiated or determined in the ROD, the sampling method and statistical requirements must be clearly articulated before design and implementation of the corrective measures or remedial alternatives.

Risk management decisions during the design phase of a CERCLA or RCRA remediation should be flexible, considering the uncertainty in the risk assessment results, acceptable risk range, confidence level of toxicity data or criteria to support the assessment, engineering feasibility, reliability of the measures (operational changes vs. pollution control equipment), state and community acceptance, and cost. It is recommended that risk managers and site decision-makers request input from all members of the project team for pros and cons of proposed control measures to address the short-term risks.